CONSENT FORM FOR PARTICIPATION IN NON-INTERVENTIONAL HUMAN RESEARCH STUDY

Study Title: 'Correlation of Lewis Erythrocyte Antigens with the Risk of Venous Thromboembolic Disease'

Coordinating Investigator-Scientifically Responsible:

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Principal Investigators:

- Eleni Georgiadi Assistant Professor of Hematology, Faculty of Medicine, School of Health Sciences, University of Thessaly
- Apostolos Nousias Auxiliary Registrar of Blood Transfusion Dept.-Hematology Clinic, PGNH of Larissa
- Lemonia Skoura, Pathologist, Registrar B' of Blood Transfusion Dept.-Hematology Clinic, PGNH of Larissa
- Ioannis Tsourveloudis Director of NHS Blood Transfusion Dept.-Hematology Clinic, PGNH of Larissa

Supervisor:

Paraskevi Kotsi, Hematologist, Director of Blood Transfusion Dept.-Hematology Clinic, PGNH of Larissa, Associate Professor of Transfusion Medicine, Faculty of Medicine, School of Health Sciences, University of Thessaly

Study Conducting Center:

Blood Transfusion Department of the University General Hospital of Larissa

Dear All,

You are invited to take part in a monocentric scientific clinical study carried out by the Coordinating Investigator, the Principal Investigators and the Clinically Responsible (jointly the "Research Team"). The Scientific Team would like your voluntary assistance, which is crucial for the conduct of the research.

STUDY PURPOSE

Primary objective

Investigation of the potential correlation of Lewis system antigens with venous thromboembolic disease (VTED).

Secondary objectives

Development of a clinico-biological risk assessment model (score) for first onset of VTED or its recurrence.

Inclusion criteria for the study

Adult patients aged 18-78 years with a personal history of deep venous thrombosis and/or Pulmonary Embolism.

Exclusion criteria

1. Current pregnancy or postpartum period
2. Hepatic insufficiency
3. Alcoholic cirrhosis

SUMMARY OF THE STUDY PROCEDURE

Each patient participating in the study will undergo the usual blood draws required for their regular monitoring at the Outpatient Hemostasis Disorders Clinics of PGNH Larissa. No additional blood draws will be performed for the study, nor will supplementary volume of blood be collected. One general blood vial will be stored at 2-6° C and at a 2nd time the patient will be phenotyped for the Lewis a and b antigen system.

Total study duration: 12 months.

WHAT WILL HAPPEN TO ME IF I TAKE PART:

Your participation in this study does not change the therapeutic treatment you will follow in any way. You will not be required to take any other medication that is not part of the treatment plan already prescribed by your attending physician or to have any other blood tests beyond those associated with your treatment and/or regular monitoring. Your participation in this study will have no impact on the treatment recommended by your attending physician.

DO I NEED TO TAKE PART:

Your participation in this study is voluntary. If you decide to take part, you will need, in addition to your consent below, to sign the document "INFORMATION AND CONSENT FOR DATA PROCESSING FOR SCIENTIFIC RESEARCH", if you agree, so that the Research Team has access to your data held by the Clinic, and to process this data, along with other data collected directly from you, for the purposes of the research. The processing of personal data will take place in accordance with the provisions of the currently applicable legislation.

If you do not wish to take part in the study, we assure you that this will not change your treatment by the attending Physicians in any way.

I have been informed and consent to participate in the scientific study	**I have been informed and do not consent to participate in the scientific study**
☐	☐

If you consent below as well as in the document "INFORMATION AND CONSENT FOR DATA PROCESSING FOR SCIENTIFIC RESEARCH", after the end of the research study, the samples may be used for further analyses not described in the study protocol, in the context of investigating risk factors for Venous Thromboembolic Disease with the aim of promoting scientific knowledgeIn this case, the following apply:

(a) your relevant decision is on a voluntary basis and without any financial compensation,

(b) given the rapid developments in medical science, the Research Team cannot predict exactly what research might be done on the above collected samples/remaining blood. In any case, any such research will be done in the context of investigating Venous Thromboembolic Disease with the sole purpose of promoting scientific knowledge,

(c) the Research Team will not contact you regarding the results of this or future research that may be conducted on the above samples,

(d) any samples will be stored, anonymously or coded, with limited access, and will not be marked with information that directly links them to your person,

(e) the above samples will not be sold or used to produce products for commercial exploitation and

(f) in the event that you consent, as below, you have the right to withdraw that consent at any time, by informing the Research Team in writing, at which point the above samples will not be used for the above purpose (further analyses).

I have been informed and consent to the use of the collected samples/remaining blood for further analyses in the context of investigating risk factors for venous thromboembolic disease, with the aim of promoting scientific knowledge.	I have been informed and do not consent to the use of the collected samples/remaining blood for further analyses in the context of investigating risk factors for venous thromboembolic disease, with the aim of promoting scientific knowledge.
☐	☐

WHAT ARE THE RISKS OF THE STUDY

You run absolutely no risk from your participation in this study because it is a non-interventional observational study and there is no possibility of adverse reactions related to it.

Thank you very much for your participation.

Larissa, ____

Patient's full name and signature:

_____

Date: _ / _ / ____

Full name and signature of Physician Responsible for Information and obtaining consent:

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